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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,979	03/22/2001	Gary de Jong	24601-416	7635

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/815,979	Applicant(s) DE JONG ET AL.	
	Examiner Daniel M. Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2005 and 14 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-32,34-47,59,61-64 and 144-147 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-29 and 34-47 is/are allowed.
- 6) ☒ Claim(s) 1,3-14,30-32,59,61-64 and 144-147 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/14/053</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Papers filed 14 October 2005 and 14 December 2005 in response to the Non-Final Office action mailed 11 April 2005. Claims 1-32, 34-47, 59, 61-64 and 144-147 were considered in the 11 April Office Action. Claim 2 was canceled and claims 1, 11, 14, 15, 26, 28, 34 and 35 were amended in the 14 December Paper. Claims 1, 3-32, 34-47, 59, 61-64 and 144-147 are pending and under consideration.

Response to Amendment and Arguments

Rejection of claim 2 is rendered moot by the cancellation thereof.

Claim Rejections - 35 USC § 112

Rejection of claims 11 and 26-29 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

Rejection of claims 34, 35, 41-43 and 47 under 35 U.S.C. 102(b) as being anticipated by Unger *et al.* (1997) *Invest. Radiol.* 32:723-727 as evidenced by the Mediatech, Inc. Formulations Table for Dulbecco's Modification of Eagle's Medium is **withdrawn** in view of the amendment of claim 34 such that the method is limited to delivering a large nucleic acid molecule.

Claims 1, 3, 4, 6, 7, 9, 10, 12-14 and 30-32 **stand rejected** and claim 11 is **newly rejected** under 35 U.S.C. 102(b) as being anticipated by Marschall *et al.* (1999) *Gene Ther.*

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6:1634-1637 as evidenced by Lipofectamine™ Reagent product description, available from Invitrogen™ life technologies or Transfectam™ Reagent product description, available from Promega for the reasons set forth at pages 4-7 of the 11 April Office Action and herein below.

Response to Arguments

In response to the *prima facie* case of record, Applicant contends in the arguments commencing on page 14 of 18 and continued through the second paragraph on page 16 of 18 that the claims are not anticipated by Marschall *et al.* because the serum free medium used in the method of Marschall *et al.* cannot be construed as a delivery agent. In particular, Applicant contends that the serum free medium is not used to increase permeability of cells.

This argument has been fully considered but is not deemed persuasive. Office personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). As stated in the previous Office Action, “The limitation ‘delivery agent’ is defined on page 13 of the specification as, ‘compositions, conditions or physical treatments to which cells and/or nucleic acids may be exposed in the process of transferring nucleic acids to cells in order to facilitate nucleic acid delivery into cells’...[The culture medium is construed as a “delivery agent” because] the culture medium can reasonably be viewed as a composition that facilitates nucleic acid delivery into cells because it provides a medium through which the nucleic acid is contacted with the cell” (page 4). The interpretation of the claim limitation is fully consistent with Applicant’s own broad definition of “delivery agent” in the specification.

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With regard to “increasing permeability”, it noted that the claims are not limited to applying a delivery agent that enhances permeability of the cell. The relevant portions of claim 1 recite, “(b) adding a second delivery agent to a composition containing the cell or applying a delivery agent to the cell” and, “the second delivery agent, when added to the cell composition, enhances permeability of the cell”. Thus, the claim requires that either a second delivery agent is added to a composition containing the cell or a delivery agent (not necessarily the second delivery agent) is applied to the cell, wherein the claim only requires that the second delivery agent, if used, enhances permeability of the cell. As the claims do not require that the second delivery agent be used, the claims are not limited to adding a delivery agent that enhances permeability of the cell to the nucleic acid. Therefore, Applicant’s arguments with regard to enhancing permeability are not persuasive, at least, because the claims do not require that the cells be contacted with a delivery agent that enhances permeability.

Applicant’s arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §102(b) as anticipated by the art.

With regard to claim 11, the claim was left free of the art because it required that ultrasound or electrical energy be applied to the cell as an agent that enhances permeability. As amended, claim 1 recites the addition of an agent that enhances permeability as an alternative embodiment (*i.e.* the “second delivery agent”, which might be substituted by “a delivery agent”). Therefore, the limitation to applying ultrasound or electrical energy to the cell is now reasonably construed as an alternative embodiment of claim 11 that is not required for anticipation of the claim as a whole and the new rejection is necessitated by Applicant’s amendment.

Claim Rejections - 35 USC § 103

Claims 1-10, 12-14, 30-32, 59, 61-64 and 144-147 **stand rejected** and claim 11 is **newly rejected** under 35 U.S.C. 103(a) as being unpatentable over Hadlaczky *et al.* (2/2000) US Patent No. 6,025,155 (previously made of record) in view of Marschall *et al.* (*supra*) as evidenced by Lipofectamine™ Reagent product description (*supra*) or Transfectam™ Reagent product description (*supra*) for the reasons set forth at pages 8-10 of the 11 April Office Action and herein below.

Response to Arguments

Applicant's arguments with regard to the instant obviousness rejection are again based on the assertion that the culture medium used in the methods disclosed in the art cannot be construed as a delivery agent.

These arguments are not persuasive because, as discussed above, the interpretation of the claim is fully consistent with Applicant's own broad definition of "delivery agent" in the specification and, with regard to "increasing permeability", the claims do not require that a delivery agent that increases permeability be used. Therefore, Applicant's arguments with regard to enhancing permeability are not persuasive, at least, because the claims do not require that the cells be contacted with a delivery agent that enhances permeability.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §103(a) as obvious over the art.

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With regard to claim 11, as discussed above, the claim was left free of the art because it required that ultrasound or electrical energy be applied to the cell as an agent that enhances permeability. As amended, claim 1 recites the addition of an agent that enhances permeability as an alternative embodiment (*i.e.* the “second delivery agent”, which might be substituted by “a delivery agent”). Therefore, the limitation to applying ultrasound or electrical energy to the cell is now reasonably construed as an alternative embodiment of claim 11 that is not required by the claimed invention as a whole and the new rejection is necessitated by Applicant’s amendment.

Allowable Subject Matter

Claims 15-29 and 34-47 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636


DANIEL M. SULLIVAN
PATENT EXAMINER